



Procedures and Data Requirements for approval of Food Additives in India

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MINISTRY OF LAW AND JUSTICE
(Legislative Department)

New Delhi, the 24th August, 2006/Bhadra2, 1928(Saka)

The following Act of Parliament received the assent of the President on 23rd August, 2006, and is hereby published for general information:-

FOOD SAFETY AND STANDARDS ACT, 2006

No. 34 OF 2006

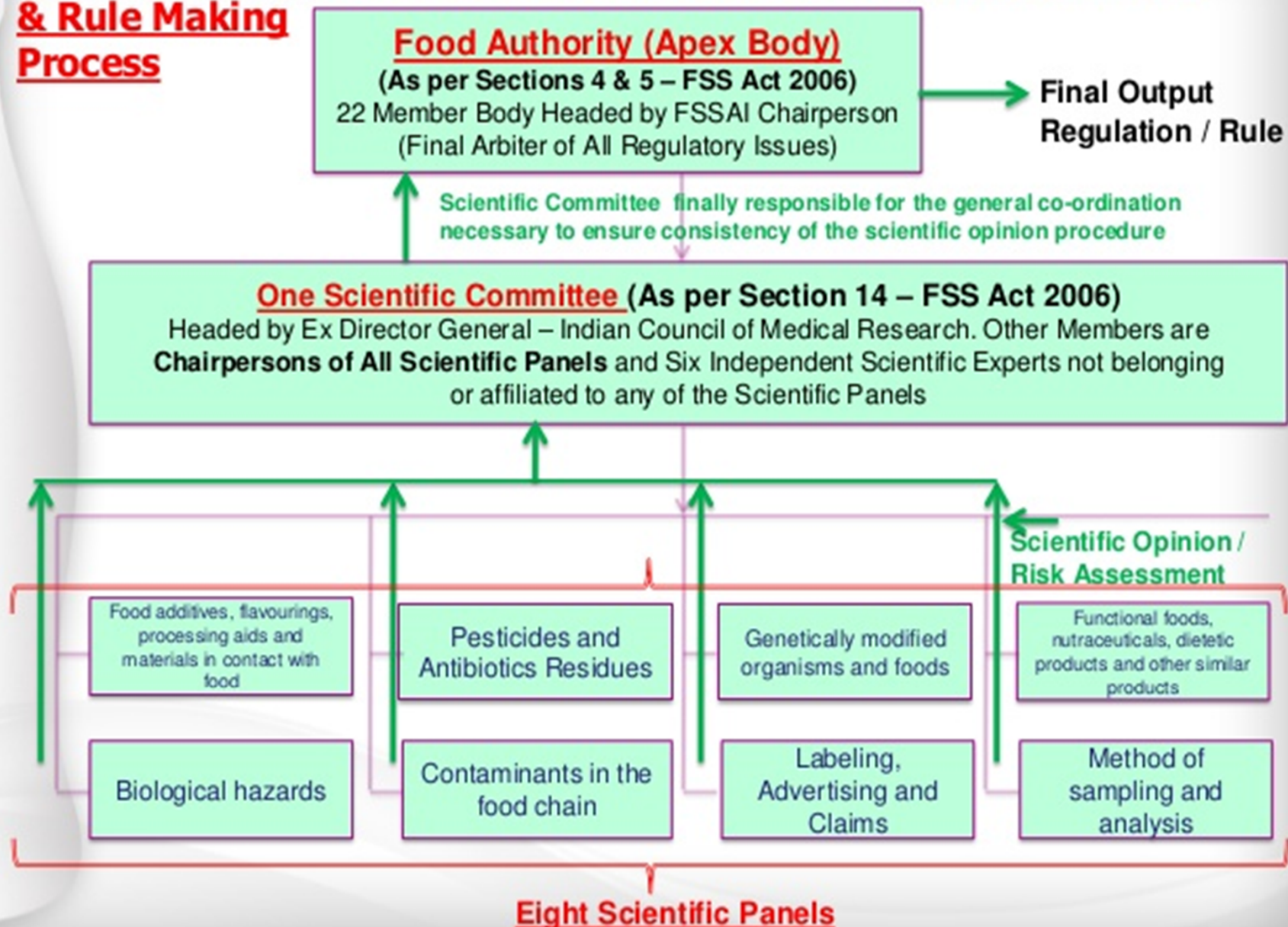
[23rd August, 2006]

An Act to consolidate the laws relating to food and to establish the Food Safety and Standards Authority of India for laying down science based standards for articles of food and to regulate their manufacture, storage, distribution, sale and import, to ensure availability of safe and wholesome food for human consumption and for matters connected therewith or incidental thereto.

Food Safety & Standards Act: Integrates



FSSAI - Robust Scientific Risk Assessment to drive Regulation & Rule Making Process



Scientific Panels at FSSAI-Current Status

- Panel for Functional Foods, Nutraceuticals, Dietetic Products and other similar products
- Panel for Method of Sampling and Analysis
- **Panel for Food Additives, Flavourings, Processing Aids and Materials in contact with Food**
- Panel on Contaminants in Food Chain
- Panel for Biological Hazards
- Panel for Pesticides and Antibiotic Residues
- Panel for Labelling and Claims/Advertisements
- Panel on Genetically Modified Organisms and Foods
- Panel for Fish and Fisheries Products
- Panel on Sweets, Confectionery, Sweeteners, Sugar & Honey:
- Panel on Water (including flavoured water) & Beverages (alcoholic non-alcoholic)
- Panel on Oils & Fats
- Panel on Milk and Milk Products
- Panel on Meat and Meat Products including Poultry
- Panel on Cereals, Pulses & Legume and their Products (Including Bakery)
- Panel on Fruits & Vegetables and their Products (Including Dried Fruits and Nuts, Salt, Spices and Condiments)
- Panel on Nutrition and Fortification

Concerns on Food Additives

- **Food additives have been the subject of public policy, regulatory activity as well as public interest for decades**
- **Misplaced concerns due to-**
 - **Long unfamiliar names similar to complex chemical compounds**
 - **Motive of economic adulteration**
 - **Misbranding**
 - **Improving the perceived quality**
 - **Use of unsafe additives**
 - **Using safe additives beyond permissible limits**

Food Additive Approval Process in India

- **Application in a structured format**
- **Details of additive requested**
 - Name of food categories
 - Level of usage
 - Technological justification
 - Current status under local regulations
- **JECFA and other safety evaluations**
- **CODEX approval status and other regulatory agencies**
- **Questionnaire to include information on:**
 - Technical information such as chemical name, CAS number, chemical and structural formula
 - Specifications for identity and purity of substance
 - Chemical and physical properties
 - Method of analysis

What happens when an application is received from an industry

- The FSSAI's secretariat in Standards division studies the proposal for its merit for taking the expert scientific opinion.
- The proposal in the form of an agenda is placed before the scientific panel.
- The deliberations in the panel center around
 - i) Technological need of the additive in the particular food category and the likely processing conditions,
 - ii) Safety studies and data,
 - iii) The quality specifications with respect to residual chemicals and solvents therein,
 - iv) The analytical protocol used for quantification of the said additive,
 - v) The implications, if any, on labeling,
 - vi) The extent of consumption of a said food type and hence the likely consumption of the concerned additive, and
 - vii) Regulatory status in CODEX, JECFA and other standards such as EFSA.

Flow sheet for inclusion of an additive in the regulations

- **If the scientific panel is convinced on the technological need and safety of the additive, it is recommended for approval of the scientific committee of FSSAI.**
- **After approval of the scientific committee, a draft regulation is prepared and forwarded to the Food Authority for its approval.**
- **The approved draft is then sent to regulation division of FSSAI for forwarding to the Ministry of H&FW.**
- **The draft regulation after legal vetting is then published for public comments within a specific time period.**
- **The public comments are collated by the FSSAI secretariat and once again placed before the scientific panel for their views.**
- **The panel may accept a comment based on its merit and after due deliberation recommend required changes in the draft before its final notification.**
- **The process may take around 6-9 months.**

FSSAI-Harmonization Exercise

In March 2013

- FSSAI embarked on a major harmonization exercise
- Currently, several standards in FSSR, 2011 have been drawn from provisions of the erstwhile PFA Act
- Development of new standards and tests, where necessary
- WTO encourages harmonization of national food regulatory standards. guidelines and best practices with those of CODEX
- Based on regular requests for review of these standards taking in to account
 - Latest developments in food science across the globe
 - Food consumption pattern, new specifications
 - Presence of new contaminants and toxins
 - Use of new food additives required by the producers and manufacturers in food business

Food Harmonization *vis-à-vis* Food Equivalence???

Current status

- **Contemporary food science and technology have contributed greatly by integrating many other disciplines to enhance food safety, biology, chemistry, physics, engineering, materials science, microbiology, nutrition, toxicology, biotechnology, computer science, genomics**
- **Safe, nutritious, convenience, tasty, diverse foods at affordable prices available today**
- **Made possible with advances in technology, specifically, food additives**

Working groups

- **Working group:** is a group of experts working together to achieve specified goals.
- The groups are domain-specific and focus on discussion or activity around a specific subject area.
- Examples of common goals for working groups include:
 - A parliamentary working group
 - Creation of an informational document
 - Creation of a standard
 - Resolution of problems related to a system
 - Continuous improvement
 - Research
- **Examples related to food additives:** Processing aids, trehalose, colors

Some concluding remarks

- **Approval is an ongoing process**
- **Additives for Indian traditional foods need extensive data base**
- **Certain additives used traditionally are non-existent in other standards – need attention**
- **Can be facilitated with proper supply of data**
- **Cannot be at the expense of excluding competitors**

Thank
you